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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,653	10/19/2001	Ralph-Heiko Mattern	INT-0004	2405

7590 09/09/2003
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EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

101 002 653

Applicant(s)

Xacton et al

Examiner

Kraft

Group Art Unit

1057

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6/23/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-13 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-13 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 file 6 1/29/02
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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In a response of 6/23/03 to a restriction requirement of 5/21/03, applicants added new claim 13, and elected Group I claims 1-4, and claim 13 with traverse. On reconsideration in view of applicants' traverse, the restriction requirement is withdrawn.

5 Claims 1-13 are examined on the merits, which are all claims in the application.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is
10 required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01 (page 600-60).

For example, see page 8, line 28. If these symbols are for U.S. Patents, the patent numbers should be listed instead. Any other hyperlinks or codes should be deleted, or replaced with a U.S. Patent
15 Number if a patent is intended.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

25 Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a scaffold matrix and method for producing and using the scaffold matrix wherein the scaffold matrix comprises a collagen/glycosaminoglycan co-precipitate

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that has been crosslinked with glutaraldehyde at a density sufficient to stabilize the scaffold matrix to terminal sterilization by exposure to E-beam radiation at about 15 to about 80 kGy so the scaffold matrix retains characteristics to function as a structural support for cell
5 and tissue growth, does not reasonably provide enablement for any composition containing collagen and glycosaminoglycan sterilized by any method and retaining any characteristics to function as any matrix or scaffold. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly
10 connected, to make and use the invention commensurate in scope with these claims.

The claimed invention must be commensurate in scope with the invention enabled by the specification. The specification demonstrates encountering a problem only when sterilizing a specific
15 composition containing collagen and glycosaminoglycan by a specific electron beam radiation method, and enables overcoming the problem only when using a specific crosslinking method for the composition containing collagen and glycosaminoglycan.

Claim Rejections - 35 USC § 112

20 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his
25 invention.

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Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 Bridging lines 1 and 2 of claim 1, "collagen a glycosaminoglycan" is uncertain as to meaning and scope.

The claims are confusing and unclear as to the composition, matrix or scaffold required by the claims due to the vagueness and breadth of the claims in regard to the characteristics of the
10 composition, matrix or scaffold and the procedure used for sterilization of the composition, matrix or scaffold.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the
20 subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner
25 presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention

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was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being
5 unpatentable over Yannas et al (4,060,081) or (4,280,954) in view of Cheung et al (AA).

The claims are drawn to a composition and method for producing and using the composition wherein the composition comprises cross-linked collagen and glycoaminoglycan that retains characteristics to
10 function as a matrix or scaffold following terminal sterilization.

Yannas et al disclose producing a composition for use as a scaffold containing crosslinked collagen and glycoaminoglycan matrix, and sterilizing the crosslinked collagen and glycoaminoglycan matrix. For example, see '081 (paragraph bridging cols 20 and 21) and '954
15 (col 23, lines 19-37).

Cheung et al disclose using gamma irradiation to sterilize bioprosthesis comprising collagen (page 581). At 1 Mrad dosage, insignificant damage occurred (page 581, abstract). The use of gamma radiation has an advantage of sterilizing after a container is sealed
20 and not introducing toxic substances during the process (line 7 from the last line on page 581).

It would have been obvious to use gamma radiation for the sterilization of the crosslinked collagen/glycoaminoglycan matrix of Yannas et al to obtain the advantage of this sterilization as

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disclosed by Cheung et al. When the dosage of radiation is sufficiently low, characteristics would be retained as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yannas et al (4,060,081) or (4,280,954).

The invention and references are described above.

The crosslinked collagen/glycoaminoglycan matrix of Yannas et al is inherently crosslinked sufficiently to retain characteristics after sterilizing as required by the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is 703-308-0196.



David M. Naff
Primary Examiner
Art Unit 1651

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15 DMN
9/8/03